REMARKS

Claims 1-35 are pending in this application. Claims 1-17 have been withdrawn as being directed to non-elected subject matter. Claim 18 has been amended. Claim 35 has been newly added.

Claim 25 has been amended for the sole reason of advancing prosecution. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert the original claim scope of any claim amended herein, in a continuing application.

Claim 18 has been amended to recite "[a] sponge for iontophoretic administration of charged drugs to a tissue of a subject, comprising: a porous structure configured and operable to absorb and hold at least 30% w/w aqueous solutions without dissolving or disintegrating, the porous structure comprising a surface area of contact with the tissue; and a data transmitting module configured and operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject." Support for claim 18, as amended, can be found throughout the specification and claims as originally filed.

Claim 35 has been newly added. New claim 35 is directed to "[t]he sponge according to claim 18, wherein the surface area of contact is a substantially planar surface." Support for new claim 35 can be found throughout the specification and claims as originally filed. For example, please *see* Figure 1.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 18-22, 26-29 and 31-34 have been rejected under 35 USC § 102(b) as being anticipated by Sun et al. (US Publication No. 2002/0115957).

The Examiner asserts that Sun et al. teach, either expressly or inherently, every element of claims 18-22, 26-29 and 31-34.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 18 is directed to a ***sponge*** for iontophoretic administration of charged drugs to a tissue of a subject, comprising: a porous structure configured and operable to absorb and hold at least 30% w/w aqueous solutions without dissolving or disintegrating, ***the porous structure comprising a surface area of contact with the tissue***; and a data transmitting module configured and ***operable to transmit data indicative of one or more of sponge size and the surface area of contact of the sponge with the tissue of the subject.***" (Emphasis added). Claims 19-22, 26-29 and 31-34 depend, either directly or indirectly, from claim 18,

In contrast, Sun et al. is directed to an apparatus for transporting a compound through a barrier membrane of a mammal. The apparatus according to Sun et al. require: a vessel having a membrane contacting surface, ***the surface having a plurality of exposed blades and a channel adjacent to said blades***; a reservoir in communication with said channels for storage of said compound; and an electrode in communication with said reservoir, wherein the width of said blades are tapered away from said surface. *See* Sun et al. at the abstract.

However, Applicants submit that sun does not anticipate claims 18-22, 26-29 and 31-34 because Sun et al. do not describe: (1) a sponge; (2) a sponge having surface area of contact with the tissue; (3) a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating; or (4) a data transmitting module configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with a tissue of the subject.

With regard to item (1), Applicants submit that the "sponge-like *material*" described in Sun et al. at paragraph 50 is merely a fluid carrier maintained in an internal reservoir or chamber. The terminology "sponge-like" merely suggests some resemblance to a sponge. In this regard, Applicants note that the term sponge-like is defined by Merriam Webster Dictionary as, "resembling a sponge: spongy, porous." (A copy of the Merriam Webster Dictionary definition is available upon request of the Examiner). Applicants note that the general terminology utilized by Sun et al. does not provide a teaching of a sponge material. In this regard, Applicants submit that the "sponge-like material' should not be equated with a "sponge."

With regard to Item (2), Applicants submit that Sun et al. do not describe a sponge having surface area of contact with the tissue. According to Sun et al., the vessel comprises a membrane contacting surface ***which contains a plurality of exposed blades***. In Sun et al., the blades are in contact with the tissue; however, the "sponge-like" material is not, in any configuration, configured to come into contact with a tissue. *See* Sun et al. at Figures 7, 8A-D and 9. Applicants note that the structure of the device in which contact with the tissue is affected by rigid blade structure and not by a sponge of any kind.

With regard to item (3), Applicants submit that the blades required by Sun et al. are in contact with the tissue; therefore, the electronic element described by Sun et al. (in any of its configurations) cannot describe a data transmitting module "...configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with the tissue of the subject," as recited in claim 18.

It is clear from the reading of Sun et al that a contact between the blades and the tissue is necessary in order to affect delivery of an active drug therethrough. The sponge-material is not an independent portion of the device capable by itself of delivering the drug. In fact, the device of Sun et al may not even use a sponge material at all.

Regarding Item (4), Applicants submit that the structure of the device shown in Fig 7, 8A-D and 9 of Sun et al. require a plurality of exposed blades/channels that do not have varying size or surface area with the tissue. In this regard, Applicants submit that according to Sun et al., there is no varying parameter of size or surface area with

the tissue. Therefore, Sun et al. do not teach "... indicative of the sponge's size or surface area...," as recited in claim 18.

In further support of the patentability of the presently claimed subject matter, Applicants submit that Sun et al. also do not teach or suggest that the "fluid carrier" does not dissolve or disintegrate, as claimed. Further, Applicnats submit that Sun et al. do not teach that the "fluid carrier" has at least 30% w/w of an aqueous solution. While a sponge according to the presently claimed subject matter must not dissolve or disintegrate in order to operate, the fluid carrier of Sun et al. does not provide this structural feature as it is maintained in an internal reservoir or chamber.

In view of the above, it is submitted that Sun et al. do not teach, either expressly or inherently, each and every element of claims 18-22, 26-29 and 31-34, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 3 of the Official Action, claims 23-25 and 30 have been rejected under 35 USC § 103(a) as being unpatentable over Sun et al. in view of Nicolais et al. (US Patent No. 5,645,592)

The Examiner asserts that it would have been obvious to modify the sponge of Sun et al. by coating it with a HEMA-methyl methylacrylate copolymer as allegedly taught by Nicolais et al.

In view of the following these rejections are respectfully traversed.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more

than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a prima facie case of obviousness has not been established because, whether taken alone or together, the cited references do not teach or suggest every element of the claimed subject matter as required by *In re Wilson*. In addition, applicants submit that there is no motivation to modify Sun et al. to arrive at the present subject matter because doing so would change the principle of operation required by Sun et al.

Claims 23-25 and 30 each depend, either directly or indirectly, from claim 18. Both independent claim 18 and Sun et al. are discussed in detail above. As discussed, Sun et al. do not teach or suggest (1) a sponge; (2) a sponge having surface area of contact with the tissue; (3) a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating; or (4) a data transmitting module configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with a tissue of the subject.

Nicolais et al. do not remedy the deficiencies of Sun et al. In contrast to the present subject matter, Nicolais et al. is directed to orthopedic fasteners and replacements including, for example, nails, screws, pins, hip and knee replacements, etc., coated with hydrogels and other biocompatible/biodegradable materials. *See* Nicolais et al. at the abstract.

However, like Sun et al., Nicolais et al. do not teach or suggest do not teach or suggest (1) a sponge; (2) a sponge having surface area of contact with the tissue; (3) a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution without dissolving or disintegrating; or (4) a data transmitting module configured and operable to transmit data signal indicative of one or more of sponge size or surface area of contact of the sponge with a tissue of the subject. Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In addition, Applicant submits that there is no motivation to modify the device described in Sun et al. to be without the blades required throughout the disclosure provided by Sun et al. In this regard, Applicants submit that absent the blades, Sun et al. would not be operable at all.

In addition, Applicants note that contrary to the assertions made by the Examiner, the device described by Sun et al. could not be used on a sensitive tissue, such as the surface of the eye. In Sun et al., a device/vessel comprises a membrane contacting surface which contains a plurality of exposed blades with a channel adjacent to the blades (channels which transport the drug). When the membrane contacting surface contacts a barrier membrane, e.g. skin, the blades disrupt the barrier membrane to create pathways through which the channels transport the drug. Fig 7, 8A-D and 9 of Sun et al clearly demonstrate that the contact with the tissue is affected by rigid blade structure.

Sun et al. describe an apparatus for transporting a compound across a barrier membrane of a mammal, "such as the skin or mucosa membrane of a human." *See*

Sun et al. at paragraph 8. It appears that the Examiner may have mistakenly confused "stratum corneum" described at paragraph 26 of Sun et al. with "cornea" as described in the present application. In this regard, Applicant notes that the stratum corneum is the the outermost layer of the epidermis (mainly made of dead cells), and the cornea is eye tissue. Accordingly, Applicants submit that the Examiner's assertion that Sun et al. is capable of being utilized on eye tissue.

Applicants note that the presently claimed sponge is configured to treat vulnerable tissue as the eye. *See* the application as originally filed at page 3 lines 24-27. The sponge *as claimed* provides improved safety during an iontophoresis process by indicating the sponge size or surface area of contact of the sponge with the treated tissue. As disclosed, for example, in Figs 2-3 (see element 140) the indication of sponge size or surface area of contact is used to set a safety maximum current during the iontophoretic process. Applicants submit that the correlation between current densities/surface area of the sponge and the adverse effect of the iontophoresis process is not taught or suggested by the Sun et al.

In view of the foregoing, it is submitted that nothing in the cited references, whether taken alone, or together, render the claimed invention obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. New Claim 35

Claim 35 has been newly added. Applicants respectfully submit that new claim 35 is both novel and non-obvious. Accordingly, Applicants respectfully request an indication that all of the pending claims are now allowable.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

Susanne M. Hopkins
Registration No. 33,247
Ari G. Zytcer
Registration No. 57,474
Customer No. 20529

Date: March 9, 2010
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
Tel: (703) 548-NATH
Fax: (703) 683-8396